ALTANA AKTIENGESELLSCHAFT
Form 6-K
October 12, 2005

Table of Contents

Form 6-K
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Report of Foreign Private Issuer
Pursuant to Rules 13a-16 or 15d-16 of
the Securities Exchange Act of 1934
Dated: October 12th, 2005
ALTANA Aktiengesellschaft
(Translation of Registrant s name into English)
Am Pilgerrain 15
D-61352 Bad Homburg v. d. Höhe
Federal Republic of Germany
(Address of principal executive offices)

Indicate by check mark whether the Registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F þ Form 40-F o

Indicate by check mark if the Registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ____

Indicate by check mark if the Registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ____

Indicate by check mark whether the Registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes o No þ

If Yes is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82-____

TABLE OF CONTENTS

Table of Contents

This Report on Form 6-K is hereby incorporated by reference into the Registrant s Registration Statements on Form S-8, dated September 13, 2002 (File No. 333-99485), dated September 24, 2003 (File No. 333-109074), dated September 24, 2004 (File No. 333-119240), and dated September 26, 2005 (File No. 333-128583).

This Report on Form 6-K contains:

Press Release of October 12th, 2005

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ALTANA Aktiengesellschaft

Dated: October 12th, 2005

By: /s/ Hermann Küllmer
Name: Dr. Hermann Küllmer
Title: Chief Financial Officer and Member of the Management Board

By: /s/ Rudolf Pietzke
Name: Dr. Rudolf Pietzke
Title: General Counsel

Table of Contents

Press release

ALTANA AG

P.O.Box 1244
61282 Bad Homburg
v.d.H.

Herbert-Quandt-Haus
Corporate
Communications
Am Pilgerrain 15
61352 Bad Homburg
v.d.H.
Germany

P +49 (0) 6172 1712-160
F +49 (0) 6172 1712-158
PR@altana.de
www.altana.com

ALTANA R&D Day 2005

London/Bad Homburg, October 12, 2005 At today s R&D Day in London, ALTANA AG (NYSE: AAA; FWB: ALT), gave an overview on the most important projects in research and clinical development of the pharmaceutical division ALTANA Pharma AG. The emphasis was on respiratory, in particular Daxas® (roflumilast) and Alvesco® (ciclesonide). In addition, R&D projects in gastroenterology (gastrointestinal tract) and oncology (cancer) were presented.

Thanks to our high R&D expenditure amounting to almost 20% of our therapeutics sales and to our focus on the core areas of gastroenterology, respiratory, inflammation, and oncology, we created a highly innovative pipeline and further advanced our clinical projects. This will contribute to strengthening ALTANA Pharma s ground-breaking power and thus create the basis for further growth in the future, said Dr. Ulrich Thibaut, member of the Management Board of ALTANA Pharma AG, who is responsible for R&D.

Comparative studies on efficiency and tolerability of Alvesco®

Alvesco® is a new generation inhaled corticosteroid with novel release and distribution properties resulting in lung-targeted anti-inflammatory effects. Inhaled corticosteroids (ICS) are considered to be the foundation of asthma treatment. They work by reducing inflammation the underlying disease process in the lungs and airways.
Today, Alvesco® has been approved in more than 30 countries. It is now available in nine countries, among others Germany, UK, the Netherlands, Australia, and Brazil. Numerous other markets are to follow later in the year, with additional market launches planned for the first half of 2006. In addition, ALTANA Pharma expects the approval for children and adolescents in Europe in 2006. In the U.S., the cooperation partner for Alvesco®, Sanofi-Aventis, filed for approval with the FDA, and in October 2004 Sanofi-Aventis received an Approvable Letter.
In total, data from more than 10,000 asthma patients were collected for Alvesco®.

Once-daily administration of Alvesco® 320 µg to patients with moderate asthma improved the lung function (FEV_1) similar to a twice-daily administration of fluticasone 200 µg. In this comparative clinical trial (M1-133) the quality of life-parameters for patients treated with Alvesco® were higher than for the patients treated with fluticasone.

A dosage of 160 µg Alvesco® per day resulted in an improvement of lung function (FEV_1) and asthma control similar to budesonide with double the dosage (400 µg/day). Gadgil et al. already presented the outcome of the study with patients suffering from moderate to severe asthma at a scientific congress.

Table of Contents

A study comparing children treated with Alvesco® 160 µg or budesonide 400 µg showed similar effects. However, the effects of Alvesco® on the HPA-axis were significantly lower which underlines Alvesco® s excellent safety profile. The study also included recording the growth of the children. During the Alvesco® therapy they grew significantly more compared to the budesonide therapy.

The most frequently reported adverse events seen in ciclesonide clinical trials were nasopharyngitis, headache, and upper respiratory tract infection.

In addition to the launched inhaler Alvesco®, the ciclesonide product family also includes ciclesonide nasal spray (phase III), and ciclesonide as a fixed combination product with formoterol (phase II).

Further phase III data on the efficiency of Daxas® for asthma and COPD

The product candidate Daxas® (roflumilast) is a selective phosphodiesterase 4 (PDE4) inhibitor for treating chronic inflammatory respiratory conditions such as asthma or COPD (Chronic Obstructive Pulmonary Disease). Data from additional phase III clinical trials demonstrate a continuous improvement of the lung function and thus confirm the results of previous trials. In total, data of 3,172 COPD patients and of 3,365 asthma patients are now available.

The first one-year COPD study RATIO/M2-112 proved the sustained improvement of lung function and a good safety profile throughout one year. The lung function (FEV_1), a primary endpoint of the study, improved significantly with a roflumilast therapy over placebo. Compared to placebo roflumilast resulted in a difference of 39 ± 12 ml (endpoint analysis; p=0.0005 o.s.) respectively 48 ± 9 ml, with a comprehensive longitudinal analysis of the data (p<0.0001). The trial included 1,513 patients with severe and very severe COPD. 62% of the patients included in the RATIO study were simultaneously treated with inhalative steroids. The improvement of the lung function was also evident in the patients who were simultaneously treated with inhalative steroids.

Another endpoint of the study was the incidence of moderate to severe exacerbations. The outcome of a primary analysis showed that the exacerbation rate was 7% lower (not statistically significant). The pre-specified secondary analysis of moderate exacerbations defined as requiring treatment with oral corticosteroids (alone or plus antibiotics) showed that roflumilast 500 µg significantly reduced moderate exacerbations (p=0.0147). The reduction was estimated to be 18% using the Poisson regression model. In this group the reduction of exacerbations was consistent, meaning it was also independent of the simultaneous use of inhalative steroids. For patients with very severe COPD (GOLD Stage IV), who have an increased exacerbation rate, the outcome of the sub-group analysis of the RATIO study was a reduction of the exacerbations by 36% for roflumilast versus placebo.

Compared to previous studies the RATIO study showed extremely low exacerbation rates.

In a second placebo-controlled study in COPD (PEGASUS1), which was primarily conducted in the United States, the improvement of lung function by roflumilast treatment was again confirmed. 909 patients were treated for 6 months with either 500 µg roflumilast once daily or placebo. The primary efficacy endpoint for the study, change from baseline to final visit in post-bronchodilator FEV_1, was statistically significant with a between-treatment difference of 70 ml, favoring roflumilast (p<0.001 o.s.).

The PRIME study, comparing roflumilast 500 µg and montelukast 10 mg in asthma patients was recently completed. This large asthma study was conducted in 10 different countries involving 957 patients treated for 6 months. Both treatments were effective in improving lung function. Non-inferiority of roflumilast to montelukast was demonstrated regarding the primary variable FEV_1.

In addition a study (ROMEO) investigating the efficacy of roflumilast 500 µg in asthma patients receiving an underlying ICS therapy (fluticasone 250 µg) was recently completed. This large asthma study included 661 patients treated for 6 months. Improvements in the primary variable FEV_1 were

Table of Contents

numerically greater for fluticasone and roflumilast 500 µg compared with fluticasone and placebo, which was significant in a pre-specified longitudinal analysis.

The known safety profile of roflumilast was not changed by these studies. The most frequent adverse effects in connection with roflumilast treatment for both indications were headaches, nausea, and diarrhea.

Gastroenterology and Oncology

In gastroenterology the latest comparative data, which will very soon be scientifically presented by Bardhan et al., show the benefits of Pantoprazole 40 mg versus Esomeprazole 40 mg when treating GERD patients. After a 12 week treatment with Pantoprazole the number of patients who were endoscopically cured was higher (statistically significant).

ALTANA Pharma not only focuses on the life-cycle management of Pantoprazole but also on so-called P-CABs (formerly APA), the next generation acid inhibitors with a better and faster mode of action than PPIs. Next to Soraprazan in phase II of clinical development there is another P-CAB in phase I.

In oncology ALTANA Pharma focuses on a portfolio of SMOL anti-cancer drugs:

Development of anti-mitotic cancer agents to substitute current taxane-based chemotherapy

Next generation of HDAC inhibitors.

ALTANA Pharma expects to be able to lead its own oncology projects into clinical phase I in the next two years.

Table of Contents

This press release contains forward-looking statements, i.e., current estimates or expectations of future events or future results. The forward-looking statements appearing in this press release include estimates for the achievement of certain milestones in the development of ALTANA s pharmaceuticals, their marketing approval, and ALTANA s expectations of further growth in the forthcoming years. These statements are based on beliefs of ALTANA s management as well as assumptions made by and information currently available to ALTANA. Many factors that ALTANA is unable to predict with accuracy could cause ALTANA s actual results, performance or achievements to be materially different from those that may be expressed or implied by such forward-looking statements. These factors include ALTANA s ability to develop and launch new and innovative pharmaceutical products, the level of ALTANA s investment in pharmaceuticals related R&D, decisions of the competent regulatory authorities, the sales and marketing methods used by ALTANA to distribute its pharmaceuticals and the composition of ALTANA s pharmaceuticals portfolio.

Forward-looking statements speak only as of the date they are made. ALTANA does not intend, and does not assume any obligation, to update forward-looking statements to reflect facts, circumstances or events that have occurred or changed after such statements have been made.

The Webcast of the R&D Day and this press release are also available on the Internet at **www.altana.com**.

For inquiries please contact:
Dr. Thomas Gauly
Head of Corporate Communications &
Investor Relations
Media Relations:
P +49 (0) 6172 1712-160
P +49 (0) 6172 1712-168
F +49 (0) 6172 1712-158
Investor Relations:
P +49 (0) 6172 1712-163
P +49 (0) 6172 1712-165
F +49 (0) 6172 1712-158
Investor Relations USA:
P +1 212 974-6192
F +1 212 974-6190